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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,309	HOFMANN, KAY	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction is required under 35 U.S.C. §§ 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Claims 1-4, drawn in part to a first product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:1, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:9 useful in a method of making the protease, and to a first method of use of the first protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

2. Claims 1-4, drawn in part to a second product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:2, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:1- useful in a method of making the protease, and to a first method of use of the second protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

3. Claims 1-4, drawn in part to a third product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:3, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:11 useful in a method of making the protease, and to a first method of use of the third protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

4. Claims 1-4, drawn in part to a fourth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:4, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:12 useful in a method of making the protease, and to a first method of use of the fourth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

5. Claims 1-4, drawn in part to a fifth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:5, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:13 useful in a method of making the protease, and to a first method of use of the fifth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

6. Claims 1-4, drawn in part to a sixth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:6, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:14 useful in a method of making the protease, and to a first method of use of the sixth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

7. Claims 1-4, drawn in part to a seventh product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:7, to a polynucleotide

encoding the protease such as the nucleic acid sequence of SEQ ID NO:15 useful in a method of making the protease, and to a first method of use of the seventh protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

8. Claims 1-4, drawn in part to an eighth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:8, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:16 useful in a method of making the protease, and to a first method of use of the eighth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

9. Claims 1-4, drawn in part to a ninth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:18, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:17 useful in a method of making the protease, and to a first method of use of the ninth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

10. Claims 1-4, drawn in part to a tenth product, an aspartyl protease comprising the amino acid sequence of SEQ ID NO:19, to a polynucleotide encoding the protease such as the nucleic acid sequence of SEQ ID NO:20 useful in a method of making the protease, and to a first method of use of the tenth protease in an assay to identify an inhibitor by measuring proteolytic activity, classified under national practice in, *inter alia*, class 435, subclass 212.

11. Claims 5, 8, and 9 drawn, in part, to an eleventh product, a structurally-undefined inhibitor capable of inhibiting the proteolytic activity of an aspartyl protease, to a composition comprising same, and to a first method of use of the composition in treating a disease related to an aberrant cleavage of an amyloid precursor protein, classified under national practice in, *inter alia*, class 514, subclass 1.

12. Claim 5, 8, and 9, drawn, in part, to a twelfth product, a nucleic acid inhibitor capable of inhibiting the expression of a transcript encoding an aspartyl protease, to a composition comprising same, and to a first method of use of the composition in treating a disease related to an aberrant cleavage of an amyloid precursor protein, classified under national practice in, *inter alia*, class 536, subclass 24.5.

13. Claim 6, drawn to a thirteenth product, an antibody capable of identifying an aspartyl protease, classified under national practice in, *inter alia*, class 530, subclass 387.1.

14. Claims 8 and 10, drawn, in part, to a second method of use of a composition comprising an eleventh product in a method of treating a disease related to an aberrant degradation of hydrophobic signal peptides, classified under national practice in class 514, subclass 2.

15. Claims 8 and 10, drawn, in part, to a second method of use of a composition comprising a twelfth product in a method of treating a disease related to an aberrant degradation of hydrophobic signal peptides, classified under national practice in class 514, subclass 44.

16. Claims 8 and 11, drawn, in part, to a third method of use of a composition comprising an eleventh product in a method of treating a disease related to an

aberrant accumulation of unfolded proteins in the endoplasmic reticulum, classified under national practice in class 514, subclass 2.

17. Claims 8 and 11, drawn, in part, to a third method of use of a composition comprising a twelfth product in a method of treating a disease related to an aberrant accumulation of unfolded proteins in the endoplasmic reticulum, classified under national practice in class 514, subclass 44.

18. Claims 8 and 12, drawn, in part, to a fourth method of use of a composition comprising an eleventh product in a method of effecting an enhanced immune response contributing to MHC recognition of hydrophobic peptides, classified under national practice in class 424, subclass 2.

19. Claims 8 and 12, drawn, in part, to a fourth method of use of a composition comprising a twelfth product in a method of effecting an enhanced immune response contributing to MHC recognition of hydrophobic peptides, classified under national practice in class 536, subclass 23.1.

20. Claim 13, drawn to a fourteenth product, a cell line, classified under national practice in class 435, subclass 235.

Inventions of Groups 1-10 lack unity of invention, one with another, because the products are structurally diverse and are not disclosed to have a common, specific, function, such as recognition of a common substrate, thus can share no technical feature that is special.

Inventions of Groups 1-10 lack unity of invention with inventions of Groups 11-20 because the eleventh through fourteenth products and their related methods of use of Groups 11-20 are not related to any products of Groups 1-10 by a method of making or a method of use and are not disclosed to share any common structural features with the products of Groups 1-10, thus can share no special technical feature with products or methods of Groups 1-10.

Inventions of Groups 11, 14, 16 and 18 lack unity of invention with inventions of Groups 12, 13, 17 and 19 because, no product of Group 11 is disclosed to have a defined structure, and the only structure that can be inferred to a product of Group 12 is that it might comprise a nucleotide, thus products of Group 11 and related methods of Groups 14, 16 and 18 need share no special technical feature with products of Group 12 and related methods do Groups 15, 17 and 19.

An invention of Group 13 lacks unity of invention with the inventions of Groups 11, 12 and 14-20 because it is not disclosed to share any feature of undefined structures of products of Groups 11 and 12, and is structurally distinct as well from a product of Group 20, thus can share no special technical feature with the products or methods of Groups 11, 12 and 14-20.

Inventions of Groups 11, 14, 16 and 18 lack unity of invention, each with the other, because undefined inhibitors required by the methods of any of these Groups act in mutually exclusive cellular compartments, thus need share no special technical feature, one with another.

Inventions of Groups 12, 15, 17 and 19 lack unity of invention, each with the other, because, while all methods require the use of a composition comprising a compound having at least one nucleotide, the remainder of the structure in the inhibitory compound of the composition is undefined and need not act in any common cellular compartment, thus need share no special technical feature, one with another.

The invention of Group 20 lacks unity of invention with inventions of Groups 11-19 because the product of Group 20 need comprise no product of Groups 11 and 12 and may not serve in any method of Groups 11-19, thus need share no special technical feature with any product or method.

Because these inventions lack unity and are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. William E. Player on June 3, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
June 4, 2004

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